



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/675,497	09/30/2003	Mark S. Ortiz	END5135-0516315	4657

7590 07/27/2006

DAVID E. FRANKLIN
FROST BROWN TODD LLC
2200 PNC CENTER
201 EAST FIFTH STREET
CINCINNATI, OH 45202

EXAMINER

POUS, NATALIE R

ART UNIT	PAPER NUMBER
----------	--------------

3731

DATE MAILED: 07/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/675,497	ORTIZ ET AL.	
	Examiner	Art Unit	
	Natalie Pous	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 2, 12, 14 and 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-11, 13 and 15-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 21 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Newly submitted claim 21 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-20, drawn to combination, classified in class 606, subclass 139.
- II. Claim 21, drawn to sub-combination, classified in class 606, subclass 153.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not require the anastomotic device as claimed. The anastomotic device is recited in the combination as intended use but is not positively claimed. Further, the combination does not require the woven tube of wire having outer loops or ends as required by the subcombination. The subcombination has separate utility such as a rivet.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 21 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Response to Arguments/Remarks

Regarding the Suyker Reference

Applicant's arguments with respect to claims 1-4, 13 and 14 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's arguments filed 5/12/06 regarding the 35 USC 103(a) rejection of claims 8, 9, 10 and 20 with respect to the combination of Suyker and Toledano have been fully considered but they are not persuasive. Applicant asserts that Toledano does not teach an "electrical illumination source and control" as one of ordinary skill in the art would understand the term. Examiner respectfully disagrees. Without any supporting structure, an "electrical illumination source and control" may refer to any electric source and control for an illuminator, including a switch on a wall, so long as the device is operably connected to the source and control. Applicant argues that Toledano does not teach a "battery power source and control switch incorporated into the handle with twisted wire pair conductors passing through the internal tube to the tapered tip with proximally directed electroluminescence material for deployment illumination." Examiner reminds applicant that for instance, claim 20 simply states, "an illuminator connected to the cannula." This does not incorporate any of the limitations set forth in applicants arguments as to why Toledano does not anticipate the claims, and as such examiner notes the argument above is moot as it is not directed to claim language. Examiner sustains that Toledano teaches an illuminator, and further it is well known in the art to provide an illuminator with a source of electricity and a control, as an

illuminator is inoperable without these. The previous 35 USC 103 rejections of claims 8, 9, 10 and 20 are sustained.

Regarding The Gifford Reference

Applicant's arguments, see pages 9-11, filed 5/12/06, with respect to Gifford have been fully considered and are persuasive. The 35 USC 102(b) rejections of claims 1, 5, 6, 13 and 15 and the 35 USC 103(a) rejections of claims 7, 11, 17, 18 and 19 with respect to Gifford have been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Kim (US 5797920) see below.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 7 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. A "syringe knife tip with a ball that translates and springedly withdraws into the veress needle" is not adequately described in the specification or the drawings. It is unclear as to what structure the term "syringe knife tip" is referring, and there is no drawing expressing this limitation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

Art Unit: 3731

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 15 recites the limitation "the first cannula" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim 13 rejected under 35 U.S.C. 102(e) as being anticipated by Suyker (US 6485496).

Regarding Claim 13, Suyker teaches a surgical instrument, comprising: a cannula (58); an actuating member (59) distally and laterally presented on the cannula for receiving a generally cylindrical anastomosis ring (1) and formed of radially spaced proximal leaves (61) which each distal leaf outwardly actuates by a cantilevered, hinged relationship to a central portion of the actuating member (59); a first control (proximal end of cannula 58) operative to compress a longitudinal end of the actuating member toward a center of the actuating member to actuate a respective portion of the received anastomosis ring; a second control (proximal end of shank 13) to compress another longitudinal end (60) of the actuating member toward the center of the actuating member to actuate the other respective portion of the received anastomosis ring forming a hollow rivet shape (Column 8, proximal lines 57-64).

Regarding Claim 15, Suyker teaches the surgical instrument of claim 13, further comprising a stationary member (57) mechanically grounding the center of the actuating member relative to the first cannula.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 1 rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as an obvious matter of design choice.

Regarding Claim 1, Suyker (see embodiment of figs. 37-40) teaches a surgical instrument for implanting an anastomotic ring device, comprising: an actuating member (14) formed of a plurality of proximal leaves (61) and a plurality of distal leaves (61, see fig. 38) which each leaf outwardly actuate by a cantilevered hinged relationship to a central portion (59, 60) of the actuating member, configured to receive an anastomotic ring (1) and moveable between a cylindrical, unactuated position (Fig. 7) and a hollow rivet forming shape (Fig. 11) in response to a compressive actuating force; a handle including an actuation mechanism for producing the compressive actuating force (Column 5, proximate lines 15-19, it is noted that although a handle is not explicitly recited for the embodiment of figs. 37-40, it is inherent that a handle connected to the shank and the sleeve is present to actuate the device, otherwise it would be obvious to one of ordinary skill in the art at the time the invention was made to provide a handle for actuating the device since it is well known in the art to provide a handle on the non-

working end of a device for actuation); an elongate cannula (58) configured to position the distal leaves on a distal side of an anastomotic opening and to position the proximal leaves on a proximal side of the anastomotic opening, and configured to transfer the compressive actuating force from the handle to the actuating member wherein the handle is further operably configured to produce the compressive actuating force by producing a proximally directed longitudinal motion and a distally directed longitudinal motion (fig. 37 to fig. 38), the device operably configured to separately transfer the proximally and distally directed longitudinal motions respectively to distal and proximal portions of the actuating member to pivot corresponding distal and proximal leaves toward each other to actuate the anastomotic ring device from a cylinder shape to a hollow rivet shape (Column 8, proximal lines 57-64).

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Suyker in view of Kim (US 5797920). Suyker teaches all limitations of claim 1, and further teaches wherein the cannula comprises a first tube (58) connected to the proximal portion of the actuating member (59), and a second member (13) slidingly received in the tube and connected to the distal portion of the actuating member (60)

Suyker fails to teach wherein the second member is a tube. Kim teaches an anastomosis device wherein the inner member connected to the distal actuating member (124) is a tube in order to insert tools for controllably expanding or contracting the size of the distal end of the device. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Suyker with a

tube configuration as taught by Kim in order to insert tools for controllably expanding or contracting the size of the distal end of the device.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Suyker as a matter of design choice. Suyker teaches all limitations of preceding dependent claim 1 as previously described, but does not teach wherein the elongate cannula further comprises a third tube interposed between the first and second tubes and distally engaged to a central portion of the actuating member. It would have been an obvious matter of design choice to provide Suyker with a third tube since it appears that the device of Suyker performs the task of actuating the proximal and distal elements toward each other while the center portion remains stationary equally well as that disclosed in the application, and it has been held that omission of an element and its function in a combination where the remaining elements perform the same functions as before involves only routine skill in the art. In re Karlson, 136 USPQ 184.

Claims 5, 6 and 17 rejected under 35 U.S.C. 103(a) as being unpatentable over Suyker in view of Kim (US 5797920).

Suyker teaches all limitations of preceding dependent claims 1 and 13, but fails to teach wherein the device comprises an enterotomy creation tip distally coupled to the actuating member. Kim teaches wherein the distal end of the device comprises an enterotomy creation piercing tip (130) in order to create an insertion opening for the anastomosis ring and deploy the ring with the same device. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the distal

end of Suyker with a enterotomy creation piercing tip as taught by Kim in order to create an insertion opening for the anastomosis ring and deploy the ring with the same device.

Claims 7, 11, 17, 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Suyker and Kim and further in view of Yeatman (US 6451029) and further as a matter of design choice.

The combination of Suyker and Kim teaches all aspects of preceding dependent claims 1, 5, 6 and 13 as previously described, but fails to disclose wherein the instrument comprises a pneumatic conduit communicating between the distal tip and the handle for inflating a body lumen, and the tip comprising a veress needle. Yeatman teaches an intestinal stapling device wherein a pneumatic conduit (26) is in communication with the distal tip and handle (30) in order to provide a means of leak testing and performing anastomosis with a common instrument. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Suyker and Kim with a pneumatic conduit communicating between the distal tip and the handle for inflating a body lumen as taught by Yeatman in order to provide a means of leak testing and performing anastomosis with a common instrument.

Regarding the limitation wherein the piercing tip comprises a veress needle, it is noted that a veress needle is one that serves to insufflate a body cavity for a laparoscopic procedure. It is further noted that the combination of Suyker, Kim and Yeatman as described above fulfills that description, and therefore fulfills the structure and function of a veress needle.

Claims 8, 9, 10 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suyker in view of Toledano (US 5855312) and further as a matter of design choice. Suyker teaches all aspects of preceding dependent claims 1 and 13 as previously described, but fails to disclose wherein the instrument comprises an electrical illumination source and control operably connected to the cannula proximate to the distal portion of the actuating member, the actuating member comprises a light transmissive material. Toledano teaches a medical stapling device wherein an illuminator (76) and control is operably connected proximate to the distal portion of the actuating member, the actuating member (11) comprises an optical fiber bundle (70) connected to the cannula and terminates in a translucent light transmissive head (25) in order to emanate light from the end of the device and illuminate the surrounding tissue. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the actuating member of Suyker with an illumination source connected to the cannula proximate to the distal portion of the actuating member, the actuating member comprising a light transmissive material as taught by Toledano in order to emanate light from the end of the device and illuminate the surrounding tissue.

Regarding the limitation requiring an electrical illumination source and control operably connected proximate to the distal portion of the actuating member, although Toledano does not explicitly recite an illumination source and control, Toledano teaches an illuminator (76) that is operably connected (82) proximate to the distal portion of the actuating member, and it is inherent that an illuminator is well known to power an illuminator electrically and provide a control to turn the illuminator on or off.

Regarding the limitation wherein the actuating member comprises an electroluminescent material, it would have been obvious matter of design choice to modify the combination of Suyker and Toledano by having the actuating member comprise an electroluminescent material since applicant has not disclosed that an electroluminescent material provides an advantage over translucent material, and it appears the translucent material would perform equally well to illuminate the surrounding tissue as electroluminescent material.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie Pous whose telephone number is (571) 272-6140. The examiner can normally be reached on Monday-Friday 8:00am-5:30pm, off every 2nd Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NRP
7/19/06


(JACKIE) TAN-UYEN HO
PRIMARY EXAMINER

7/24/06